

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
13 November 2003 (13.11.2003)

PCT

(10) International Publication Number  
WO 03/092574 A1

(51) International Patent Classification<sup>7</sup>: A61J 1/10

(21) International Application Number: PCT/JP03/05327

(22) International Filing Date: 25 April 2003 (25.04.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
2002-128336 30 April 2002 (30.04.2002) JP  
2002-229704 7 August 2002 (07.08.2002) JP  
2003-38927 17 February 2003 (17.02.2003) JP

(71) Applicant (for all designated States except US): OTSUKA  
PHARMACEUTICAL FACTORY, INC. [JP/JP]; 115,  
Aza Kuguhara, Tateiwa, Muya-cho, Naruto-shi, Tokushima  
772-8601 (JP).

(72) Inventors; and

(75) Inventors/Applicants (for US only): NAGAO, Kat-  
suyoshi [JP/JP]; 48-1, Aza Nanatanda, Wada, Kokufu-cho,

Tokushima-shi, Tokushima 779-3121 (JP). YOKOYAMA,  
Toshiharu [JP/JP]; 526-25, Kamojima, Kamojima-cho,  
Oe-gun, Tokushima 776-0010 (JP). KAWAKAMI, Keiichi  
[JP/JP]; 15-21, Aza Nishinosu, Tainohama, Kitajima-cho,  
Itano-gun, Tokushima 771-0200 (JP).

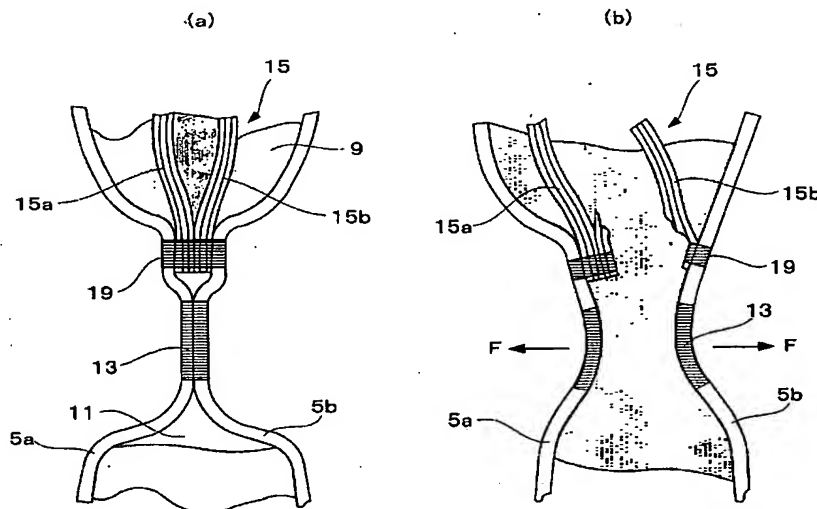
(74) Agents: SAEGUSA, Eiji et al.; Kitahama TNK Building,  
1-7-1, Doshomachi, Chuo-ku, Osaka-shi, Osaka 541-0045  
(JP).

(81) Designated States (national): AE, AG, AL, AM, AT, AU,  
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,  
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,  
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KR, KZ, LC, LK,  
LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX,  
MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE,  
SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ,  
VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),  
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,  
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,

[Continued on next page]

(54) Title: MULTIPLE-CHAMBER MEDICAL CONTAINER AND BAG FOR ENCLOSING SAME



(57) Abstract: A multiple-chamber medical container (1) comprises a container body (5) having two chambers (9, 11) for containing medicaments the rein and a partitioning weak seal portion (13) for separating the chambers (9, 11) from each other, a medicinal outlet portion (7) attached to the container body (5) for discharging the medicaments from the chambers therethrough, and an openable small container (15) disposed in the first chamber (9) and having a medicament enclosed therein, the partitioning seal portion (15) being openable so as to cause the chambers (9, 11) to communicate with each other for use. The small container (15) can be opened by opening the partitioning weak seal portion (13).



SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

**Published:**

— *with international search report*

## DESCRIPTION

### MULTIPLE-CHAMBER MEDICAL CONTAINER AND BAG FOR ENCLOSING SAME

5

#### TECHNICAL FIELD

The present invention relates to multiple-chamber medical containers for individually enclosing therein different kinds of unstable medicaments which would undergo changes with time when mixed together and which can be mixed together in an aseptic state without producing any extraneous matter by opening a seal portion for partitioning the chambers.

#### BACKGROUND OF THE INVENTION

15 Patients undergoing surgery of digestive organs are generally unable to orally receive nourishment and therefore usually subjected to intravenous hyperalimentation (IVH). For IVH, carbohydrates, amino acids and electrolytes serving as nutrients are usually given, whereas for example if glucose and amino acids are preserved as enclosed in a single container, 20 the mixture becomes brown due to the so-called Maillard reaction. Accordingly, these different kinds of medicaments need to be contained separately. For this reason, medical containers having a plurality of chambers for enclosing such medicaments 25 are introduced into wide use in recent years.

Such a medical container comprises two chambers, for example, for respectively enclosing a parenteral solution containing amino acids and a parenteral solution containing glucose, and

a seal portion partitioning these chambers separately. The seal portion is so adapted as to usually close a space between the two chambers and to open the space for use. When one of the chambers is pressed for use, an increased internal pressure  
5 of the chamber opens the seal portion to mix the medicaments in the two chambers together. When a conduit is then connected to an outlet provided in the container, the medicinal mixture can be given to the patient.

When IVH is used over a long period of time, it has been  
10 pointed out that the patient suffers from deficiencies of trace elements or vitamins which are not contained in the parenteral composition. However, since vitamin preparations are low in stability, it has been difficult to incorporate the vitamin preparation into the parenteral composition for IVH. To resolve  
15 this problem, the present applicant has proposed a multiple-chamber container as disclosed in WO, A1 No. 99/39679.

The proposed container has, in addition to the conventional structure described, a small container enclosing a vitamin preparation therein and provided inside one of the chambers.  
20 The small container can be opened by being pressed from outside. When the medical container is to be used, the seal portion is opened to mix together the medicaments in the two chambers, and the small container in the chamber is opened by being pressed from outside to mix the vitamin preparation with the mixture.

25 The construction described above nevertheless involves the necessity of opening the small container in addition to the opening of the seal portion, hence the problem of a cumbersome procedure. Especially busy places of medical services, such

a cumbersome procedure often burdens the worker heavily.

An object of the present invention, which has been accomplished to overcome this problem, is to provided a medical container comprising a plurality of chambers and adapted to  
5 readily and reliably open a small container therein.

#### DISCLOSURE OF THE INVENTION

To resolve the foregoing problem, the present invention provides a multiple-chamber medical container, the container  
10 comprising a container body having the chambers for containing medicaments therein and a partitioning seal portion for separating the chambers from one another, a medicinal outlet portion attached to the container body for discharging the medicaments from the chambers therethrough, and an openable  
15 small container disposed in at least one of the chambers and having a medicament enclosed therein, the partitioning seal portion being openable so as to cause the chambers to communicate with one another for use. The small container can be opened by opening the partitioning seal portion.

20 Thus, the small container is so adapted that it can be opened by opening the partitioning seal portion. This eliminates the need to open the small container in addition to the opening of the partitioning seal portion. The small container can therefore be opened with ease reliably,  
25 consequently reducing the burden on the worker at the busy place of medical services.

The partitioning seal portion can be formed by bonding opposed inner wall surfaces of the container body separably,

the small container being formed with a sheet material which is bonded to the opposed inner wall surfaces of the container body, the small container being openable in accordance with the separation of the inner wall surfaces caused by opening  
5 the partitioning seal portion.

The small container can be at least partly bonded to the inner wall surfaces within the partitioning seal portion or within the chamber. In the case where the small container is so bonded within the chamber, it is desirable that the distance  
10 between the small container and the partitioning seal portion be 0 to 50 mm. At this time, it is further desirable that the small container be heat-sealed at at least one portion of a peripheral edge thereof, the sealed portion being openable by an external force, a nonbonded portion of the small container  
15 inwardly of the sealed portion of the peripheral edge having a bonded portion bonded to the inner wall surfaces of the chamber.

The bonded portion of the small container can be provided by a plurality of bonded parts arranged with at least one nonbonded part positioned therebetween. Preferably, the above-mentioned  
20 at least one nonbonded part is provided in the vicinity of a center of the bonded portion.

The sheet material of the small container can comprise a multilayer film and the small container can be opened by delaminating the multilayer film. Preferably, the sheet  
25 material of the small container can comprise a multilayer film formed by laminating a plurality of resin layers having low miscibility with one another.

Alternatively, the sheet material of the small container

is at least partly heat-sealed, and the sealed portion is made openable by an external force.

With the medical container described, the small container is disposed in at least one of the chambers, whereby the medicament can be accommodated in the chamber. Even if the medicament to be accommodated in the chamber is altered in quantity, the same container body of unaltered size is usable by using a small container of different size. Further if the medicament to be accommodated is susceptible to photo-deterioration, there is no need to change the material of the entire container body, but the container body is made usable by changing only the material of the small container. The medicinal container is therefore available at a reduced production cost. The medical container can then be so designed that the medicinal outlet portion is connected to the chamber having the small container disposed therein.

The medical container described can further be provided with a discharge-control seal portion serving as an openable partition between the medicinal outlet portion and the chamber. If an attempt is made to discharge the medicament through the medicinal outlet portion in error, for example, before opening the partitioning seal portion, the flow of the medicament from the chamber can be blocked by the discharge-control seal portion, thus preventing the medicament from becoming discharged before mixing. This makes the worker to realize the proper method of using the medical container, further making it possible to discharge the medicaments only after mixing.

The present invention further provides a bag for enclosing

therein at least one multiple-chamber medical container and described above. The bag is characterized in that the bonded portion of the small container is provided approximately in parallel to the partitioning seal portion, the medical container  
5 being folded along an edge of the bonded portion on one side thereof opposite to the partitioning seal portion before being placed into the bag.

#### BRIEF DESCRIPTION OF THE DRAWINGS

10 FIG. 1 is a plane view showing a first embodiment of multiple-chamber medical container according to the invention.

FIG. 2 includes views in section taken along the line A-A in FIG. 1.

15 FIG. 3 is a plane view showing another example of multiple-chamber medical container of FIG. 1.

FIG. 4 is a plane view showing another example of multiple-chamber medical container of FIG. 1.

FIG. 5 is a view in section and showing the medical container of FIG. 1 as folded in two.

20 FIG. 6 includes fragmentary views in section and showing another example of multiple-chamber medical container of FIG. 1.

25 FIG. 7 includes views showing an exemplary process for producing the multiple-chamber medical container according to the invention.

FIG. 8 includes views showing another exemplary process for producing the multiple-chamber medical container according to the invention.



FIG. 9 is a plane view showing a second embodiment of multiple-chamber medical container according to the invention.

FIG. 10 includes a fragmentary plane view and a view in section which show another example of multiple-chamber medical container of FIG. 6.

FIG. 11 is a plane view showing a third embodiment of multiple-chamber medical container according to the invention.

FIG. 12 is a plane view showing another example of the multiple-chamber medical container according to the third embodiment of the invention.

FIG. 13 includes views showing other examples of small containers for use in the multiple-chamber medical container of the invention.

FIG. 14 is a view showing another example of small container for use in the multiple-chamber medical container of the invention.

#### BEST MODE OF CARRYING OUT THE INVENTION

Multiple-chamber medical container and embodying the present invention will be described below with reference to the drawings. Throughout the embodiments, similar parts or like parts will be designated by like reference numerals and will not always be described repeatedly.

(First Embodiment)

A first embodiment of multiple-chamber medical container of the invention will be described first with reference to the drawings concerned. FIG. 1 is a plane view of a multiple-chamber medical container according to the first

embodiment of the invention, and FIG. 2 includes views in section taken along the line A-A in FIG. 1.

As shown in FIG. 1, the medical container 1 comprises a rectangular container body 5 formed by heat-sealing two films along peripheral edge portions 3 thereof, and a medicinal outlet portion 7 joined to the container body 5 and having a rubber plug therein. The container body 5 has a first chamber 9 and a second chamber 11 which are arranged longitudinally thereof for enclosing medicaments therein. The two chambers 9, 11 are separated by a partitioning weak seal portion (partitioning seal portion) 13. The first chamber 9 has disposed therein a small container 15 containing a medicament therein as will be described later. The medicinal outlet portion 7 is connected to the second chamber 11. The end of the container body 5 opposite to the outlet portion 7 is provided with a suspending hole 17 for use in suspending the container 1.

The material of the films for the container body 5 can be any of various resin materials such as polyethylene, polypropylene, polystyrene and like thermoplastic resin. Usable is not only a film of single layer but a film of multilayer structure, such as a three-layer film comprising an inner layer and an outer layer of polyethylene, polypropylene or like polyolefin and an intermediate layer of cyclic olefin copolymer.

The partitioning weak seal portion 13 is formed by heat-sealing the two films of the container body 5 and extends in a direction approximately perpendicular to the longitudinal direction of the container body 5. The seal portion 13 is heat-sealed with such a strength as to usually separate the

two chambers 9, 11 and to be opened for use by increasing the internal pressure of the chamber for use.

The chambers 9, 11 have accommodated therein respective different medicaments a, b which need to be separated because they undergo the Maillard reaction or like change with time when mixed together or made into a solution. For example, a solution containing amino acids can be placed in one of the chambers, and a solution containing a reducing sugar in the other chamber. Further when required, electrolytes or the like can be accommodated in one of the chambers. Not only such a solution, but also other powder or solid medicament can be accommodated in one of the chambers.

The small container 15 is in the form of a bag formed by heat-sealing the peripheral edges of two multilayer films (sheet material) and has a vitamin D solution enclosed therein.

The multilayer film is a three-layer film which is susceptible to delamination and which can be prepared by sandwiching a cyclic olefin polymer layer between polyethylene layers. Also usable is a film which comprises an intermediate layer of resin having low miscibility with other resin layers and which is liable to delaminate, such as a film prepared by sandwiching a polypropylene layer between polyethylene layers. In this case, it is desirable that the innermost layer be 5 to 50  $\mu$ m in thickness. In addition to the vitamin D solution, the medicament to be enclosed in the small container 15 can be selected from among a wide variety of medicaments which are undesirable to directly mix with the medicaments in the chambers 9, 11, such as powder or liquid medicaments of antibiotics,

anticancer drugs or cardiotoxic drugs. Although not limited particularly, the liquid medicaments usable include those of vitamins or trace elements, solutions such as physiological saline and glucose solution, and parenteral compositions.

5 As shown in FIG. 2(a), the small container 15 has one end heat-sealed to the inner wall surfaces of the films 5a, 5b forming the first chamber 9, and the heat-sealed portion provides a bonded portion 19. The bonded portion 19 is positioned about 10 mm away from the partitioning weak sealed portion  
10 13, extends in parallel to the portion 13 and is thermally bonded with a strength higher than that of the weak seal portion 13 and usually not permitting separation of the bonded portion 19 like the peripheral edge portion 3 of the container body 5.

15 The multiple-chamber medical container and thus constructed will be used in the manner to be described next. To administer the medicaments within the container 1, the first or second chamber 9 or 11 is pressed as by manual pressing to increase the internal pressure of the chamber, whereby the  
20 partitioning weak seal portion 13 is opened to cause the first and second chambers 9, 11 to communicate with each other, mixing together the medicaments in the chambers 9, 11. The weak seal portion 13 is opened at this time by the separation of the films 5a, 5b of the container body 5, thereby opening the small  
25 container 15.

Stated more specifically with reference to FIG. 2(b), when the films 5a, 5b of the container body 5 separate, the resulting forces  $F$  act on the small container 15. Since the

two multilayer films 15a, 15b of the small container 15 are fixed to the films 5a, 5b of the container body 5 by the bonded portion 19, the multilayer films 15a, 15b are separated along with the films 5a, 5b of the container body 5 at this time.

5 As a result, one of the multilayer films 15a, 15b forming the small container 15 delaminates to rupture. In this way, the vitamin D solution enclosed in the small container 15 becomes mixed with the mixture of medicaments. The rubber plug of the medicinal outlet portion 7 is then pierced with a needle  
10 having a conduit (not shown) connected thereto, whereby the resulting mixture is administered to the patient through the conduit.

Thus according to the present embodiment, the multilayer films 15a, 15b forming the small container 15 are heat-sealed  
15 with a high strength to the inner wall surfaces of the first chamber 9 in the vicinity of the partitioning weak seal portion 13, so that the forces F for separating the films 5a, 5b of the container body 5 due to the opening of the weak seal portion 13 can be delivered to the small container 15 for the forces  
20 F to open the small container 15. This makes it possible to open the small container 15 with ease reliably while eliminating the need for an additional procedure for opening the small container 15 as conventionally practiced and consequently reducing the burden on the worker at the busy place of medical  
25 service.

Although the small container 15 is fixedly provided at a position 10 mm away from the partitioning weak seal portion accordingly the present embodiment, the small container 15

need not always be so positioned but can be positioned as desired.

However, it is desired that the small container be positioned at a distance of 0 to 50 mm, more preferably 3 to 10 mm, from the weak seal portion 13 so that the forces to separate the  
5 films 5a, 5b of the container body 5 can be efficiently delivered to the small container when the weak seal portion 13 is opened.

Furthermore, the small container 15 can be positioned as partly inserted into the partitioning weak seal portion 13.

Further as shown in FIG. 3, a nonbonded part 19a where  
10 the small container 15 is not bonded to the inner wall surfaces can be provided at an intermediate part of the bonded portion 19. In the case where a pressure inadvertently applied to the container body 5 acts on the bonded portion 19, this portion 19 can be relieved of the pressure through the nonbonded part  
15 19a. This prevents the pressure from acting concentrically on the bonded portion 19. The bonded portion 19 may have a structure other than the one shown in FIG. 3 insofar as this portion 19 comprises a plurality of bonded parts arranged with at least one nonbonded part 19a positioned therebetween. The  
20 nonbonded part 19a is then provided preferably in the vicinity of the center of the bonded portion 19 on which the pressure is most likely to act.

The bonded portion 19 is formed in the heat-sealed peripheral edge portion of the small container 15 according  
25 to the present embodiment. Since the small container 15 is then subjected to double heat sealing, the peripheral edge of the small container 15 appears to exhibit an impaired strength or appears liable to break. For this reason, the bonded portion

19 can be formed at a position inwardly of the peripheral edge of the small container 15 where the small container is not heat-sealed to bond the small container 15 to the container body 5 as shown in FIG. 4.

5       The multiple-chamber medical container 1 is transported usually as folded in two and placed in a bag. Accordingly, the bonded portion 19 provided at the specified position for fixedly bonding the small container 15 by heat sealing has the following advantages. The bonded portion 19 is provided  
10 in parallel to the partitioning weak seal portion 13 as shown in FIG. 5. Therefore, container 1 will be so folded that the first chamber 9 is positioned up, with the bonded portion 19 serving as a fold for folding the container 1 in two and disposed at one end of the folded container 1. Even if the first chamber  
15 9 is then pressed and thereby given an increased internal pressure, the force resulting from this pressure and to be delivered to the weak seal portion 13 is blocked by the bonded portion 19. Furthermore, folding the container 1 in two at the bonded portion 19 serves to prevent the container body 5 from inflating  
20 in the vicinity of the bonded portion 19. Consequently, the above arrangement of the bonded portion 19 can prevent the weak seal portion 13 from opening even if the chamber having the small container 15 therein is pressed on during transport.

25       The bonded portion 19 providing a fold nevertheless has the likelihood that this portion 19 will break when subjected to a force produced by the folding of the component films. Accordingly, if the container 1 is folded in two along a line L shown in FIG. 4, i.e., along the upper edge of the bonded

portion 19, the advantages described above are available, with the bonded portion 19 reliably prevented from breaking.

Although one container 1 is shown as placed in the bag F in FIG. 5, at least two containers 1 can be placed into the bag.

5 Further according to the present embodiment, the small chamber 15 is formed by the multilayer films 15a, 15b and made openable utilizing delamination, whereas single-layer films (sheet material) 15a, 15b can alternatively be used for attaching the small chamber to the container body in the following manner.

10 With reference to FIG. 6(a), the peripheral edge portion of the small container 15 is partly made openable by forming a weak seal portion 21 as by heat sealing, and the outer surfaces of the films 15a, 15b forming the weak seal portion 21 are heat-sealed to the respective inner wall surfaces of the first  
15 chamber 9 to form bonded portions 23. At this time, care must be taken so as not to impart an increased opening strength to the weak seal portion 21 by giving the heat-sealing effect for forming the bonded portions 23 to the weak seal portion 21. Stated more specifically, only the outer surfaces of the  
20 weak seal portion 21 are heat-sealed to the inner wall surfaces of the first chamber 9. This structure permits the weak seal portion 21 also of the small container 15 to be opened by opening the partitioning weak seal portion 13 as shown in FIG. 6(b).

The medicament in the small container 15 can therefore be  
25 mixed with the medicaments in the chambers reliably by a facilitated procedure. However, from the viewpoint of ease of fabrication, it is more preferable to use multilayer films because the films are liable to delaminate even if the films



of the small chamber 15 is strongly heat-sealed throughout the combined thickness of the films.

The medical container described above can be fabricated by various processes, which include, for example, the following processes.

With reference to FIG. 7, a container body is first strongly heat-sealed at opposite side portions of peripheral edge thereof to form strong seal portions 3a, and a partitioning weak seal portion 13 interconnecting the strong seal portions 3a is formed [FIG. 7(a)]. Subsequently, a small container 15 enclosing a medicament therein is placed into an upper chamber, i.e., a first chamber 9. At this time, the small container 15 is placed in as positioned close to the weak seal portion 13 [FIG. 7(b)]. A bonded portion 19 is then formed inwardly of the peripheral edge of the small container 15 to bond the small container 15 to the films forming the container body 5 [FIG. 7(c)]. The bonded portion 19 can be formed at a peripheral portion of the small container 15, i.e., at a heat-sealed portion thereof. A medicament is injected into the first chamber 9 through an opening at the upper end of the container body [FIG. 7(d)], and the first chamber 9 is thereafter sealed off by heat-sealing the upper end 3b of the container body 5 [FIG. 7(e)].

With reference to FIG. 8, a port portion is alternatively formed in an upper end portion of the container body 5 to place in the medicament through the port portion. Stated more specifically, opposite-side strong seal portions 3a and a partitioning weak seal portion 13 are formed in a container

body [FIG. 8(a)], and a small container 15 is placed into the first chamber 9 [FIG. 8(b)] and thereafter bonded to the container body in the same manner as above. The upper end 3b of the container body 5 is heat-sealed except for the part thereof for inserting the port portion therethrough [FIG. 8(c)]. Subsequently, the port portion 16 is inserted through the nonsealed part of the container body upper end 3b, and the port portion 16 is bonded to the upper end 3b by heat sealing [FIG. 8(d)]. A medicament is then injected into the first chamber 9 through the port portion 16 [FIG. 8(e)], and a plug 16a is fitted into the port portion 16 [FIG. 8(f)]. Alternatively, the medical container can be fabricated by placing in the medicament through the nonsealed part without attaching the port portion and thereafter heat-sealing this part.

As to the second chamber 11 formed by the above processes, a medicament can be placed in and a medicinal outlet portion 7 can be attached in the same manner as shown in FIGS. 8(c) to 8(f).

(Second Embodiment)

Next, a description will be given of a second embodiment of medical container comprising a plurality of chambers according to the invention. The second embodiment differs from the first in that a discharge-control weak seal portion is provided. Otherwise the present embodiment has the same construction, which therefore will not be described in detail.

With reference to FIG. 9, the multiple-chamber medical container 1 according to the present embodiment is provided with an discharge-control weak seal portion (discharge-control

seal portion) 25 serving as a partition between the second chamber 11 and the medicinal outlet portion 7. This discharge-control weak seal portion 25 is in the form of a circular arc surrounding one end of the outlet portion 7 and is formed by heat sealing with substantially the same strength as the partitioning weak seal portion 13.

The discharge-control weak seal portion 25, resembling a circular arc, may be shaped otherwise and is not particularly limited in shape insofar as this portion serves as a partition between the second chamber 11 and the outlet portion 7.

When the container 1 is to be used, the partitioning weak seal portion 13 is opened first to thereby open the small container 15 and mix the medicaments together. The discharge-control weak seal portion 25 is opened next, and the medicinal outlet portion 7 is subsequently pierced with a needle, whereupon the medicinal mixture is run off through the outlet portion 7.

The discharge-control weak seal portion thus provided has the following advantage. Conventionally, if the outlet portion 7 is pierced with a needle in error before the partitioning weak seal portion 13 is opened, there is the likelihood that the medicament within the second chamber 11 will be discharged through the outlet portion 7 before mixing, whereas when the discharge-control weak seal portion 25 is provided, the medicament in the second chamber 11 is blocked by the seal portion 25 and will not be discharged through the outlet portion 7 even if the needle pierces the outlet portion 7 before the partitioning weak seal portion 13 is opened. This directs

the worker's attention to the proper method of using the medical container, further making it possible to discharge the medicaments only after mixing.

The partitioning weak seal portion 13 and the  
5 discharge-control weak seal portion 25 need not always be nearly equivalent in opening strength; one can be lower than the other in strength. One of these portions can be made easier to open than the other, for example, by forming a projection partly on one seal portion. FIG. 10(a) shows an example wherein the  
10 partitioning weak seal portion 13 is provided at an intermediate part thereof with a V-shaped projection 27. When the second chamber 11 is pressed and thereby given an increased internal pressure as shown in FIG. 10(b), the pressure acts on the weak seal portion 13 in the directions of arrows shown. Since equal  
15 pressures act on the weak seal portion 13 perpendicular thereto at this time, the total pressure acting on the projection 27 at and around its top C is greater than the pressure in the other region of the weak seal portion 13.

Thus, the pressure acts in such directions as to separate  
20 the films forming the container body 5 as shown in FIG. 10(b), and the weak seal portion 13 starts to separate first at the top C of the projection 27 when the internal pressure in the chamber 11 further builds up. Consequently, the separation proceeds rapidly under the action of the pressure, opening  
25 the partitioning weak seal portion 13 before the discharge-control weak seal portion 25 is opened and thereby causing the first and second chambers 9, 11 to communicate with each other to mix the medicaments. Although not shown,

the small container 15 is also opened at the same time.

By providing the projection 27, the two weak seal portions 13, 25 can be made different in opening strength while permitting the weak seal portions 13, 25 to have the same width and the same bond strength. Accordingly, the two seal portions 13, 25 can be formed by heat sealing under the same conditions without the necessity of adjusting the heat-sealing time. This shortens the time required for fabricating the container 1 and results in a reduced production cost.

Besides the discharge-control weak seal portion 25 thus formed, the outlet portion 7 can be provided with a sealed portion for closing the outlet portion 7 on one side thereof closer to the second chamber 11, such that the medicament within the second chamber 11 does not reach the outlet portion 7 unless the sealed portion is subjected to an external force. While the sealed portion thus provided remains closed, the medicament within the second chamber 11 can be prevented from flowing out even if the rubber plug is pieced with the needle.

(Third Embodiment)

Next, a description will be given of a third embodiment of multiple-chamber medical container according to the present invention. This embodiment differs from the first in that no medicament is accommodated directly in the chamber wherein a small container is disposed. The embodiment otherwise has the same construction as the first and will not be repeatedly described in detail.

With reference to FIG. 11, the medical container of this embodiment has a first chamber 9 wherein the small container

15 alone is disposed, with no medicament accommodated directly therein. On the other hand, a second chamber 11 directly accommodates a liquid medicament b as in the foregoing embodiments. Thus with the present embodiment, no medicament  
5 is accommodated directly in the first chamber 9, but the small container 15 enclosing the medicament a therein is placed in the chamber 9, whereby the medicament a is accommodated in the first chamber 9. This results in the following advantage.

In the case where the medicament to be accommodated in  
10 the first chamber 9 is altered in quantity, the same container body 5 of unaltered size is made usable merely by using a small container 15 of different size. For example in the case where the medicament to be accommodated in the first chamber 9 is very small in quantity as compared with the size of the chamber,  
15 the medicament readily diffuses, so that it is difficult to mix the medicament with the medicament b within the second chamber 11 unless the medicament b is made present over the substantially entire area of the first chamber 9. On the other hand, if the small container 15 is made smaller in size in  
20 accordance with the quantity of the medicament a, the medicament can be held present concentrically at one location without diffusing. Accordingly, the medicament a in the small container 15 and the medicament b in the second chamber 11 can be mixed together reliably when the partitioning weak seal portion 13  
25 and the small container 15 are opened.

The present embodiment has another advantage. For example if the medicament a to be placed in the first chamber 9 is likely to be adsorbed by synthetic resins or is susceptible

to photo-deterioration, the amount of the medicament a will be decreased or a decomposed product will be formed. In such a case, the small container 15 is formed by films of a material to which the medicament is less likely to be adsorbed or which  
5 is less susceptible to photo-deterioration, and is accommodated in the first chamber 9. The small container 15 only can then be of a material suitable for the medicament to be accommodated.

This obviates the need to change the material of the entire container body 5 in conformity with the medicament, consequently  
10 entailing a cost reduction in the case where such a medicament as described above is to be used.

While it is likely that the medicament a to be enclosed in the small container 15 and the medicament b to be placed into the second chamber 11 of the container body 5 must be  
15 different in the method of sterilizing the medicament, the equipment for producing the container body 5 need not be provided with sterilizing equipment for practicing the two sterilizing methods because the small container can be fabricated separately from the container body 5. The medicament a for the small  
20 container 9 may be sterilized by the equipment for producing the small container 15, so that the equipment for producing the container body 5 can be provided only with the sterilizing equipment for the medicament for the second chamber 11. The production equipment can therefore be simplified.

25 Although the small container 15 is accommodated in the first chamber 9, the small container 15 can be accommodated alternatively in the second chamber 11 as seen in FIG. 12. This arrangement has the following advantage. As shown in

the drawing, no medicament is accommodated directly in the second chamber 11, but the small container 11 alone is provided in this chamber. For this reason, no medicament is discharged even if the medicinal outlet portion 7 is pierced with a needle, for example, before the partitioning weak seal portion 13 is opened. Accordingly, the medicaments to be mixed together are prevented from being discharged before mixing. Furthermore, the medicaments can be prevented from being discharged before mixing even in the absence of the discharge-control weak seal portion 25 included in the second embodiment.

As another embodiment, a medicament and the small container 15 can be accommodated in the first chamber 9, with the second chamber 11 left empty. The small container 15 can then be opened easily, while this embodiment has the above advantage of preventing the medicaments from being discharged before mixing.

Although the present invention has been described above with reference to the above embodiments, the invention is not limited to these embodiments but can be modified variously without departing from the gist of the invention. For example, the small containers to be described below can be opened with greater ease. FIG. 13(a) shows a plurality of incisions 18 formed in the lower edge of the small container 15. The forces for separating the sheets of the small container 15 can be transmitted to the peripheral edge of the small container 15 through the incisions 18, rendering the peripheral edge liable to break along the line S shown in the drawing. With the peripheral edge thus made easy to break in addition to the



delamination of the sheets, the small container 15 can be opened with greater ease. The same effect as above is available also by forming a saw-toothed lower edge 15a on the small container 15 as shown in FIG. 13(b). Alternatively, when the films for forming the small container 15 are formed by stretching a film material in the directions X shown in FIG. 13(c), the films become easy to tear along the direction X. This renders the small container 15 easier to open. Films prepared by a method other than stretching are also usable insofar as they are easy to tear along the direction X. Alternatively, a saw-toothed inner edge can be formed on the periphery of the small container as shown in FIG. 14.

The means described above can be used in a suitable combination to make the small container 15 with further increased ease. More specifically, two or all of the means shown in FIGS. 13(a) to 13(c) can be used in combination.

Although the partitioning weak seal portion 13 and the discharge-control weak seal portion 25 are formed by heat-sealing films according to the foregoing embodiments, this method is not limitative; the films can be otherwise treated in various modes insofar as they are made openable by applying an external force or forces. For example, the opposed film surfaces of the container body 5 can be provided with a ridge and a furrow, respectively, so as to fit the respective mating the ridge and furrow together separably. Alternatively, a partitioning film can be provided which is locally made smaller in thickness so as to rupture at the thin portion when subjected to a pressure and to cause the two chambers to communicate with each other.

If the small container 15 is fixedly provided in the vicinity of the film in this case, the small container 15 can be opened by separating the films of the container body 5 and thereby causing the two chambers 9, 11 to communicate with each other.

5       The bonded portion 19 for bonding the small container 15 to the films of the container body 5 need not always be in parallel to the partitioning weak seal portion 13 as previously described, or is not particularly limited in shape insofar as the forces  $F$  resulting from the separation of the films  
10 of the container body 5 can be delivered to the small container 15. The bonded portion 19, which is formed by heat sealing, can be formed otherwise or is not particularly limited in structure insofar as the small container can be reliably bonded to the container body 5 by the bonded portion.

15       The small container 15, which is formed by multilayer films or which has a weak seal portion locally in the peripheral edge thereof as described above, can be otherwise constructed insofar as the container 15 is openable by separating the films of the container body 5. For example, the small container  
20 15 can be fabricated in its entirety from thin films which can be ruptured easily.

Furthermore, the small container 15 is not limited to one in number; at least two small containers can be provided.

The chamber wherein the small container is disposed is not  
25 limited only to the first chamber 9 but can also be the second chamber 11. The small container 15 itself can be divided into a plurality of compartments by a partition or partitions.

The chambers are not limited to two in number as described

above but can be at least three. In this case, the chambers may be separated by partitioning weak seal portions like the one already described. The small container may be disposed in at least one of these chambers in the manner described above.

5       The partitioning seal portion for separating the chambers, which is a weak seal portion formed by heat-sealing the film surfaces according to the embodiments described, can alternatively be a strong seal portion which can be opened by pulling the opposed films of the container body in directions  
10       to separate these films. Even the strong seal portion ensures the same advantage as already described, i.e., the advantage that the small container can be opened by opening the strong seal portion.

## CLAIMS

1. A multiple-chamber medical container comprising:  
a container body having the chambers for containing  
5 medicaments therein and a partitioning seal portion for  
separating the chambers from one another,  
a medicinal outlet portion attached to the container body  
for discharging the medicaments from the chambers therethrough,  
and  
10 an openable small container disposed in at least one of  
the chambers and having a medicament enclosed therein;  
the partitioning seal portion being openable so as to cause  
the chambers to communicate with one another for use,  
the small container capable of being opened by opening  
15 the partitioning seal portion.

2. A multiple-chamber medical container according to claim  
1, wherein  
the partitioning seal portion is formed by bonding opposed  
20 inner wall surfaces of the container body separably,  
the small container is formed with a sheet material which  
is bonded to the opposed inner wall surfaces of the container  
body, and  
the small container opens in accordance with the separation  
25 of the inner wall surfaces caused by opening the partitioning  
seal portion.

3. A multiple-chamber medical container according to claim

2, wherein the small container is at least partly bonded to the inner wall surfaces within the partitioning seal portion.

4. A multiple-chamber medical container according to claim 2, wherein the small container is at least partly bonded to the inner wall surfaces within the chamber.

5. A multiple-chamber medical container according to claim 4, wherein the distance between the small container and the partitioning seal portion is 0 to 50 mm.

6. A multiple-chamber medical container according to claim 5 wherein,

the small container is heat-sealed at at least one portion of a peripheral edge thereof,

the sealed portion being openable by an external force, a nonbonded portion of the small container inwardly of the sealed portion of the peripheral edge having a bonded portion bonded to the inner wall surfaces of the chamber.

7. A multiple-chamber medical container according to any one of claims 4 to 6, wherein the bonded portion of the small container comprises a plurality of bonded parts arranged with at least one nonbonded part positioned therebetween.

8. A multiple-chamber medical container according to claim 7, wherein said at least one nonbonded part is provided in the vicinity of a center of the bonded portion.

9. A multiple-chamber medical container according to any one of claims 2 to 8, wherein the sheet material of the small container comprises a multilayer film and the small container  
5 is opened by delaminating the multilayer film.

10. A multiple-chamber medical container according to claim 9, wherein the sheet material of the small container comprises a multilayer film formed by laminating a plurality  
10 of resin layers having low miscibility with one another.

11. A multiple-chamber medical container according to any one of claims 2 to 5, wherein the sheet material of the small container is at least partly heat-sealed, the sealed  
15 portion being openable by an external force.

12. A multiple-chamber medical container according to any one of claims 1 to 11, wherein the small container is disposed in at least one of the chambers to thereby accommodate the  
20 medicament in the chamber.

13. A multiple-chamber medical container according to claim 12, wherein the medicinal outlet portion is connected to the chamber having the small container disposed therein.  
25

14. A multiple-chamber medical container according to any one of claims 1 to 13, wherein a discharge-control seal portion is further provided as an openable partition between

the medicinal outlet portion and the chamber.

15. A multiple-chamber medical container according to any one of claims 1 to 14, wherein a medicament selected from  
5 among an antibiotic, anticancer drug, cardiogenic drug, vitamin and trace element is enclosed in the small container.

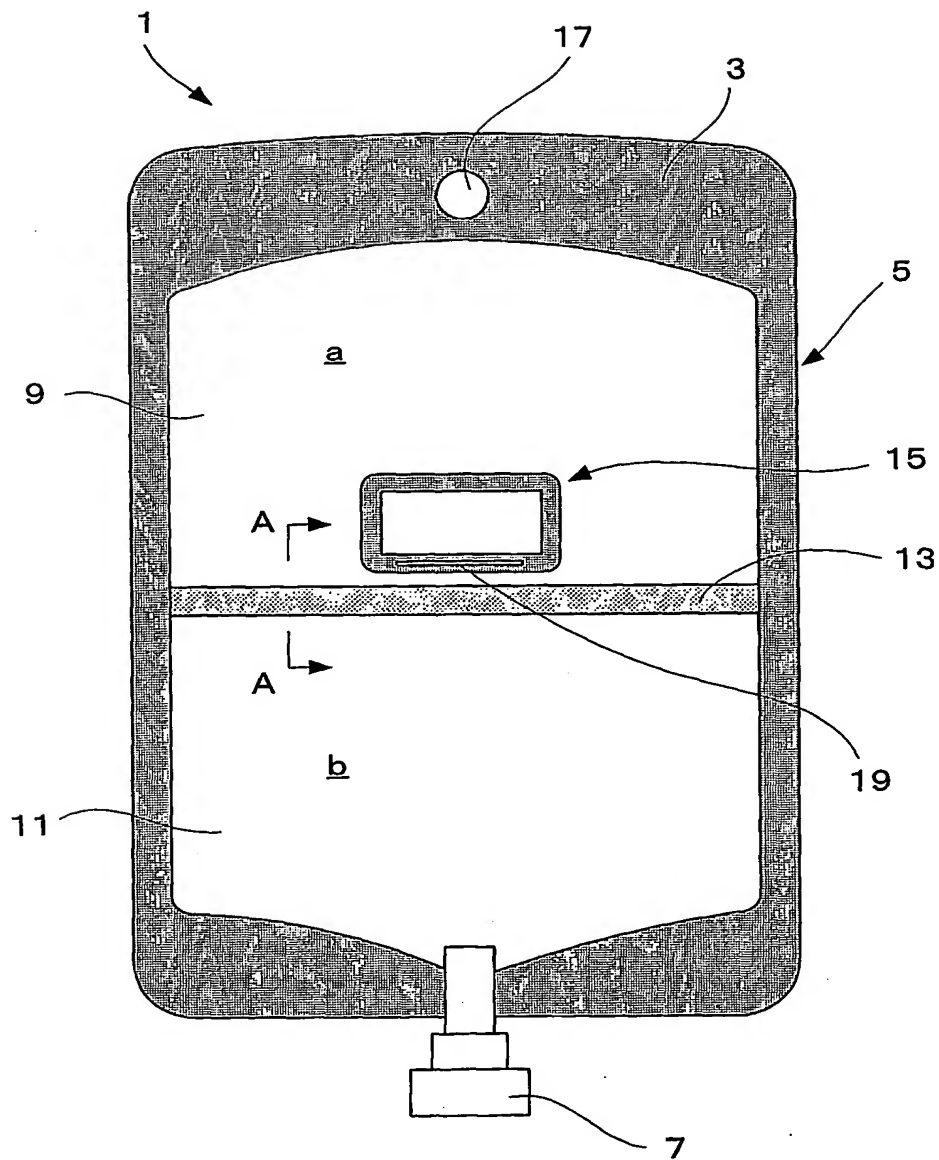
16. A bag for enclosing therein at least one multiple-chamber medical container according to any one of  
10 claims 2 to 11 wherein,

the bonded portion of the small container is provided approximately in parallel to the partitioning seal portion,

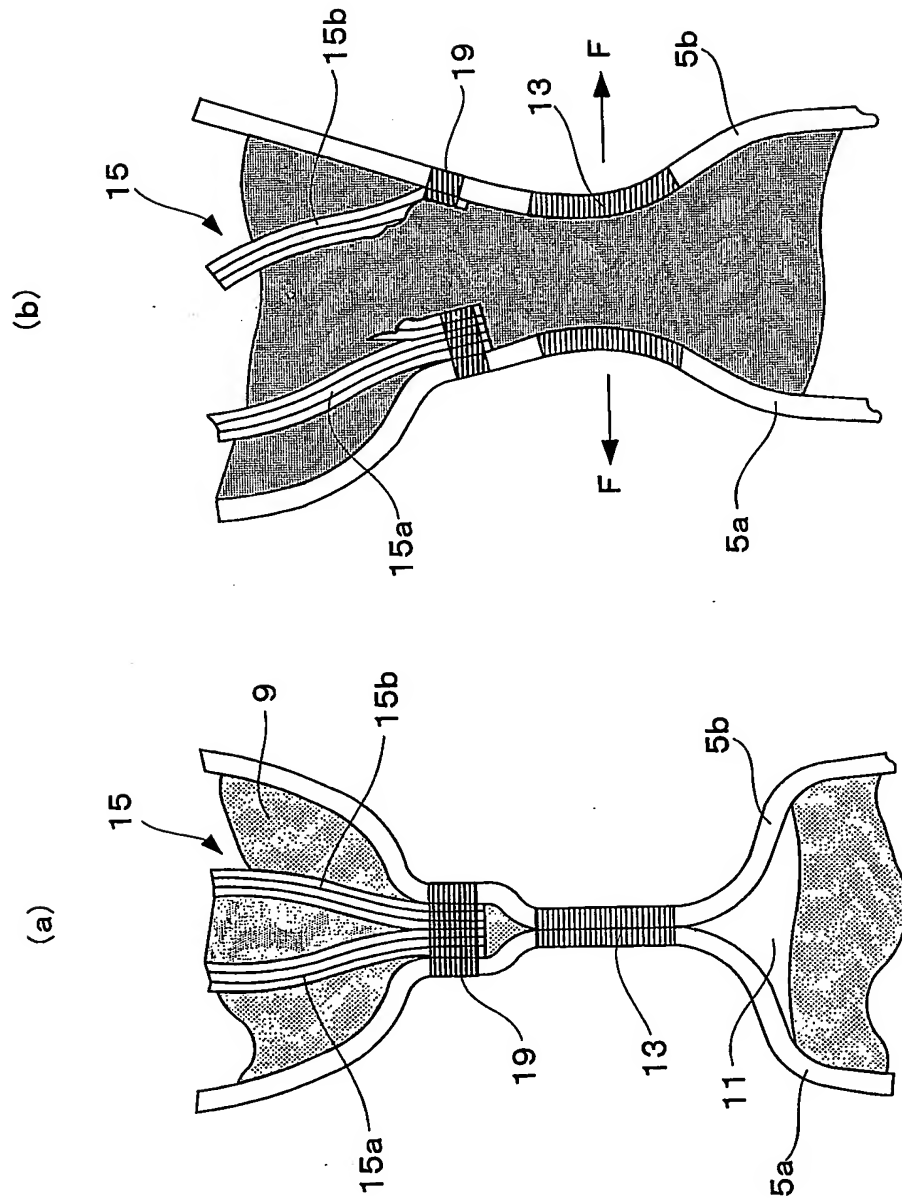
the medical container being folded along an edge of the bonded portion on one side thereof opposite to the partitioning  
15 seal portion before being placed into the bag.

1/14

Fig. 1



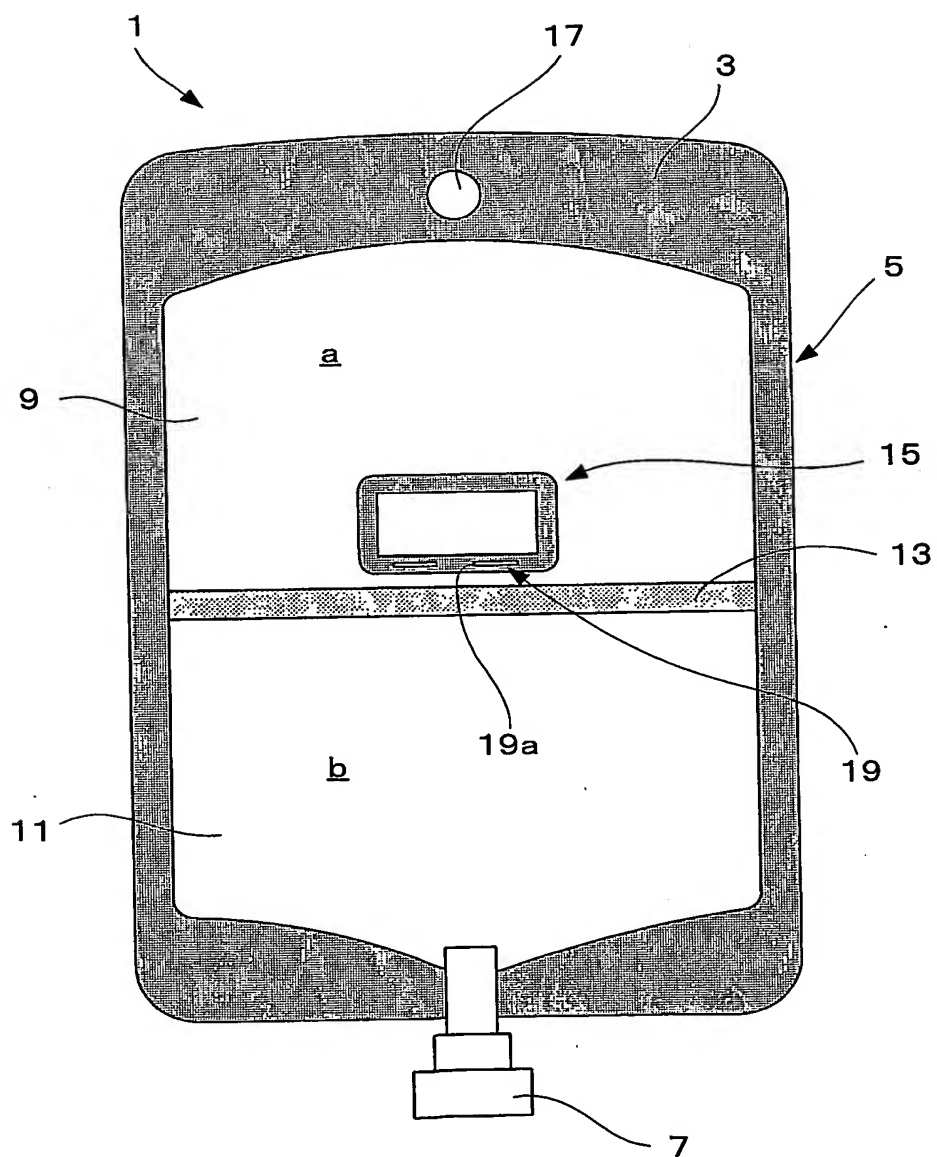




**Fig. 2**

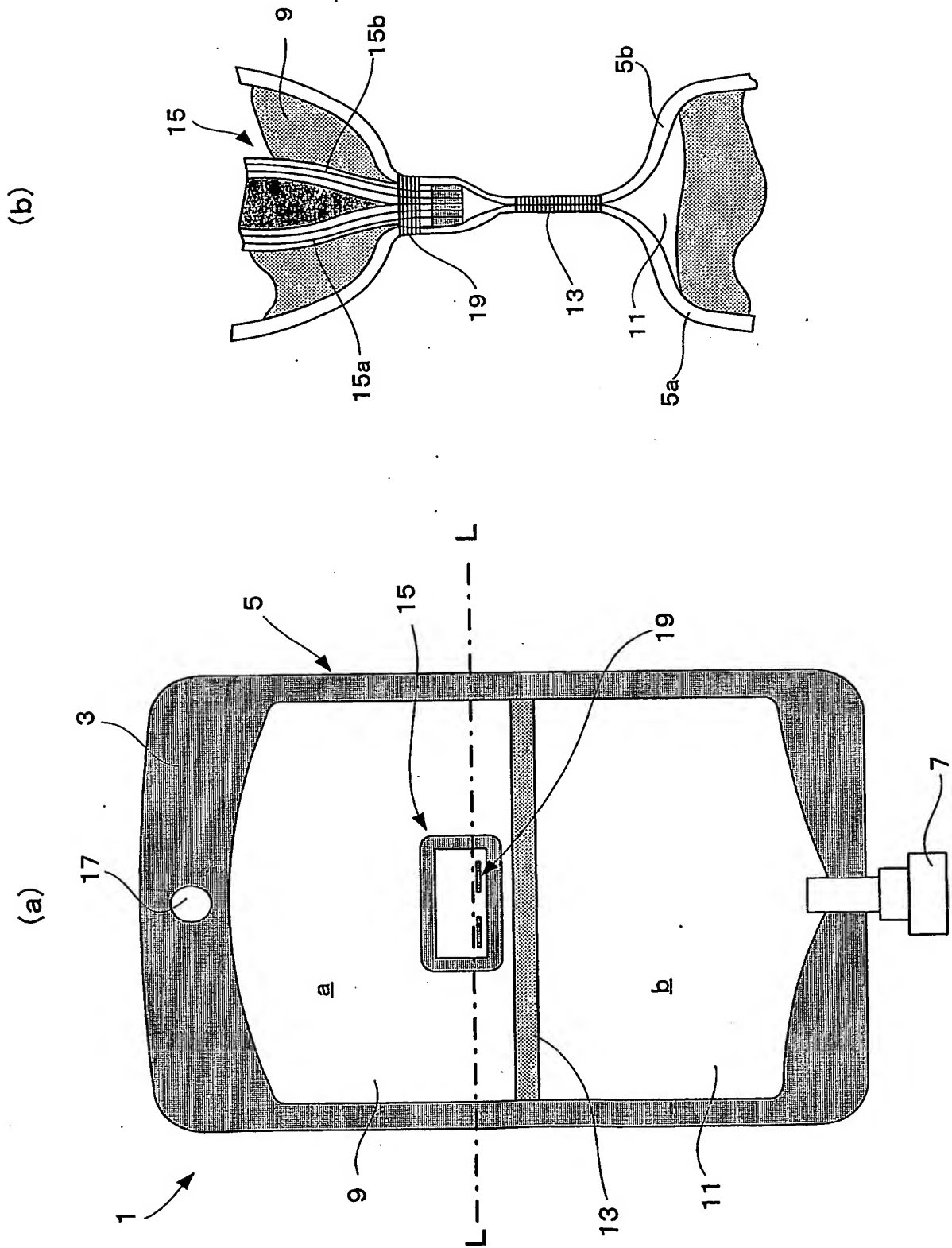
3/14

Fig. 3



4/14

Fig. 4



5/14

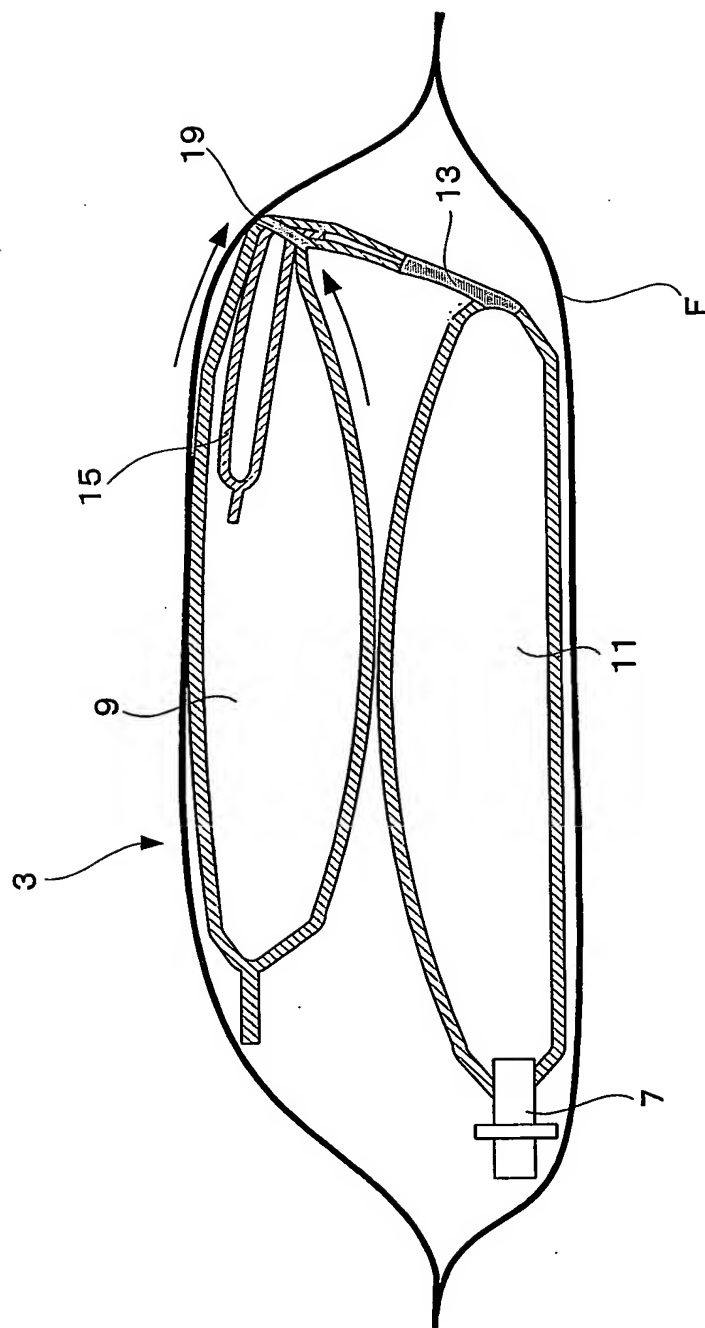


Fig. 5

6/14

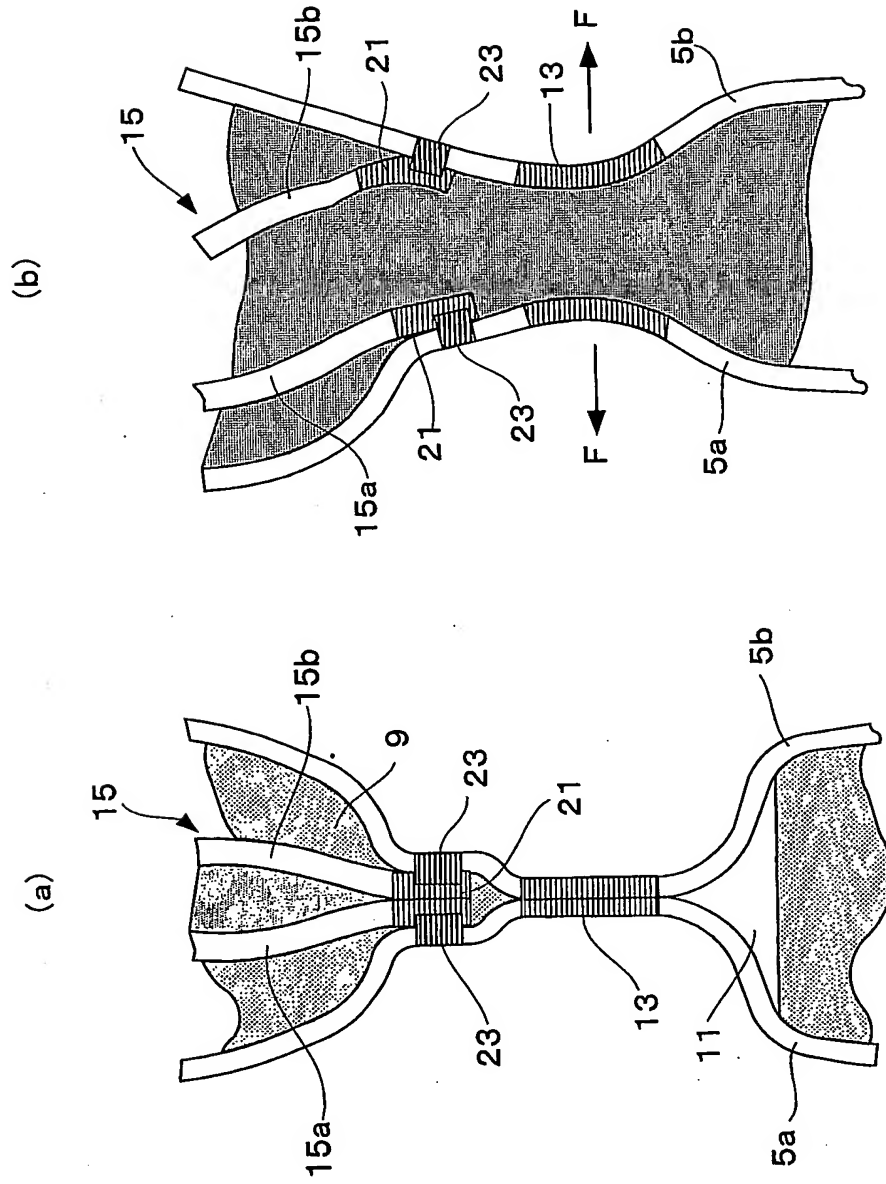
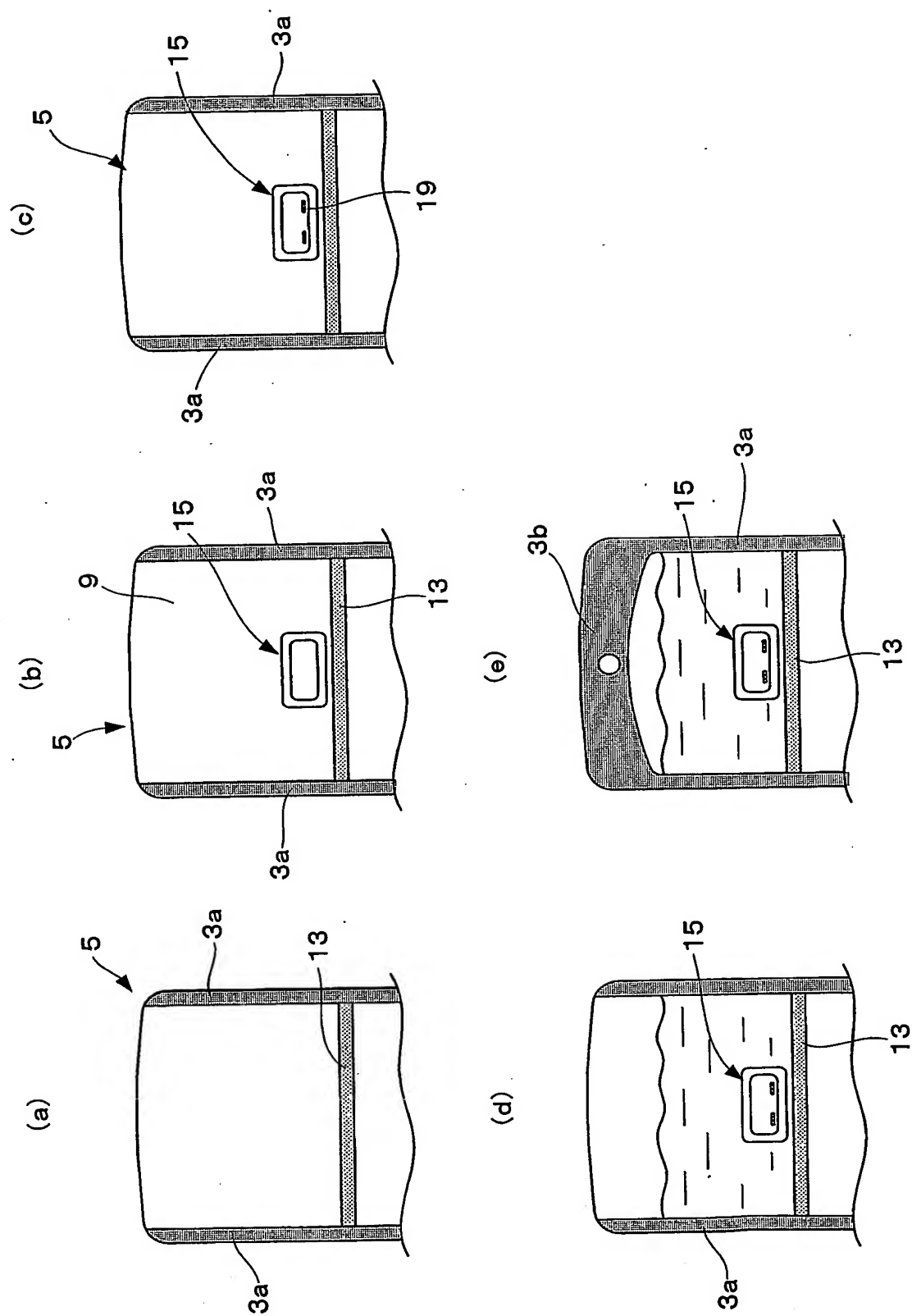


Fig. 6

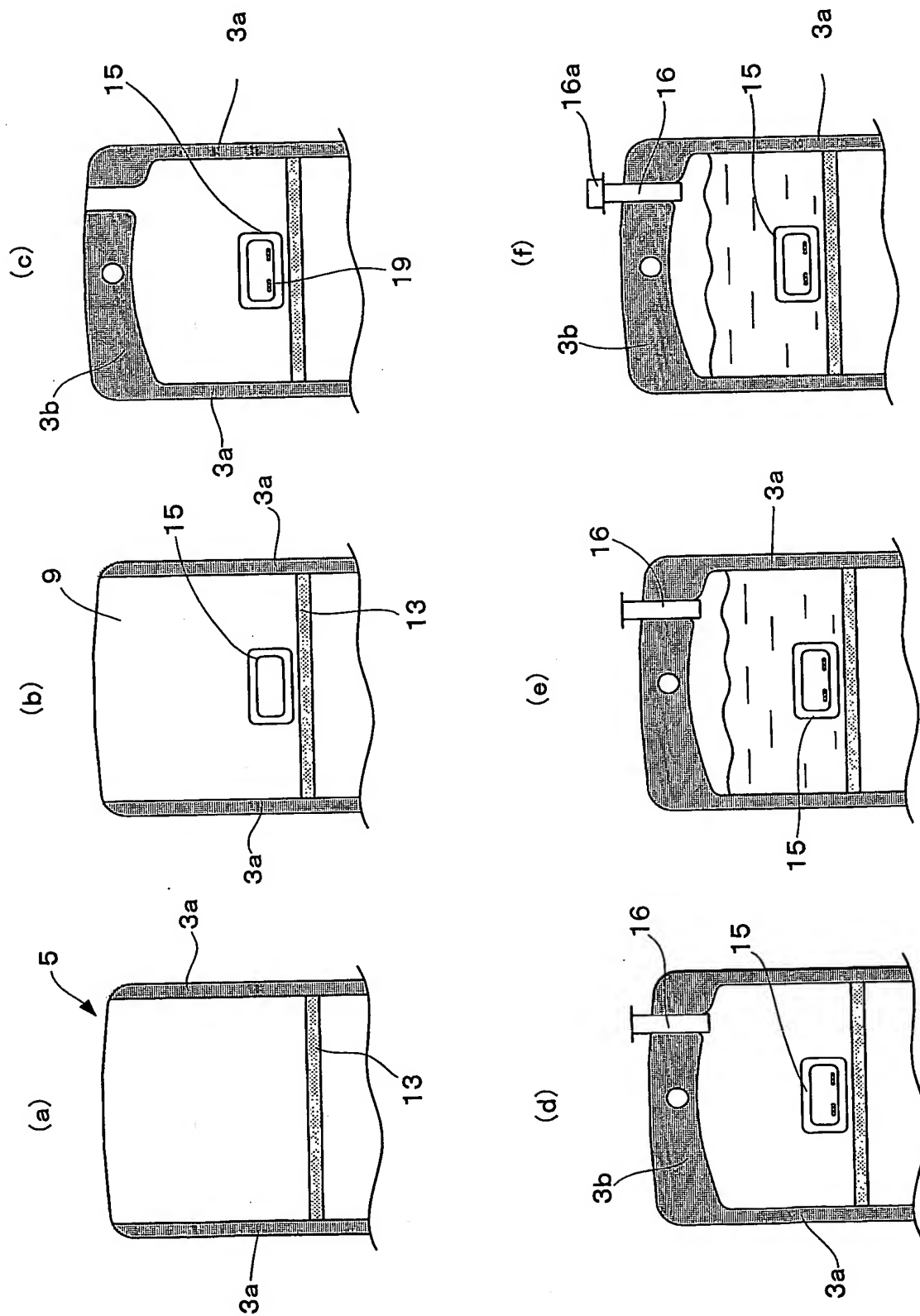
7/14

Fig. 7



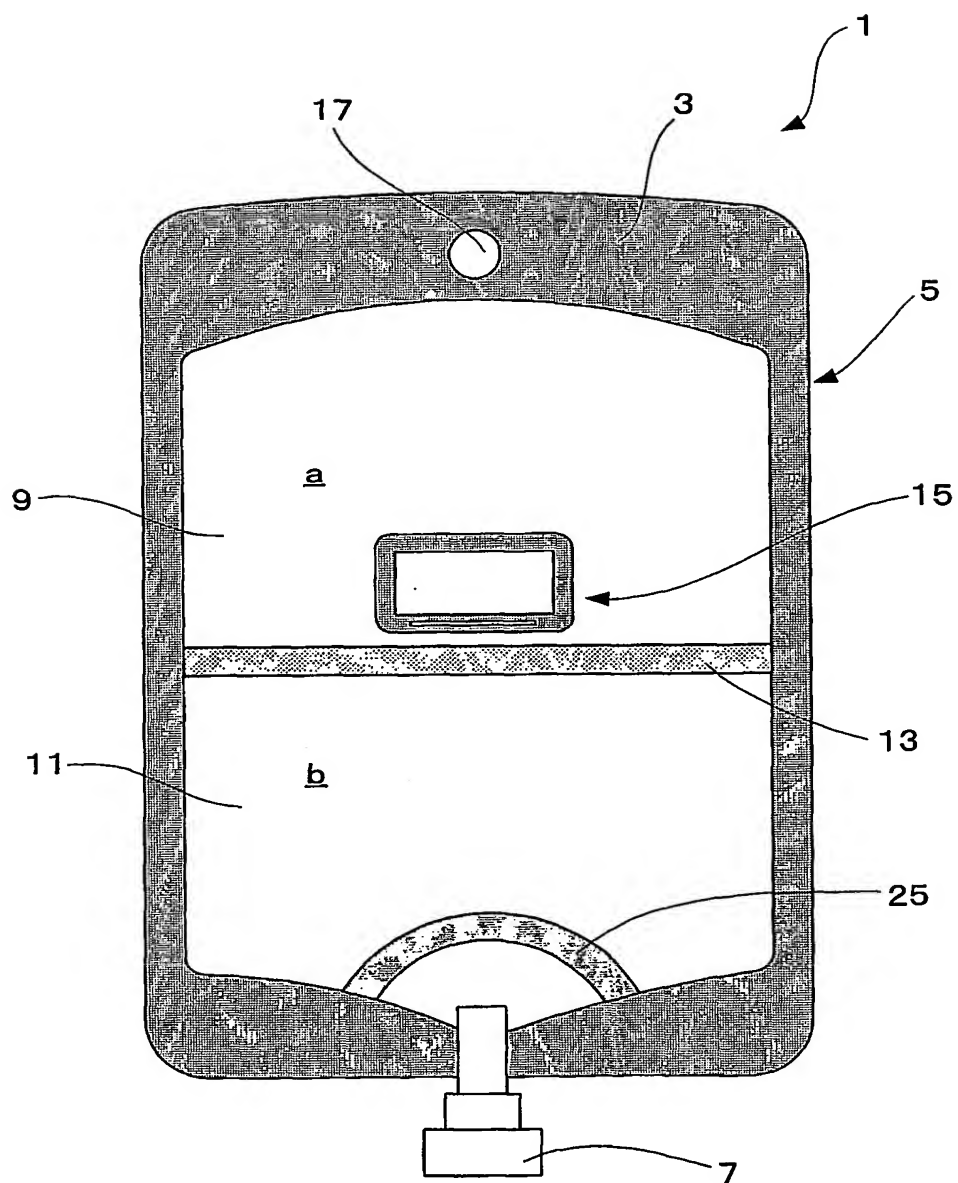
8/14

Fig. 8



9/14

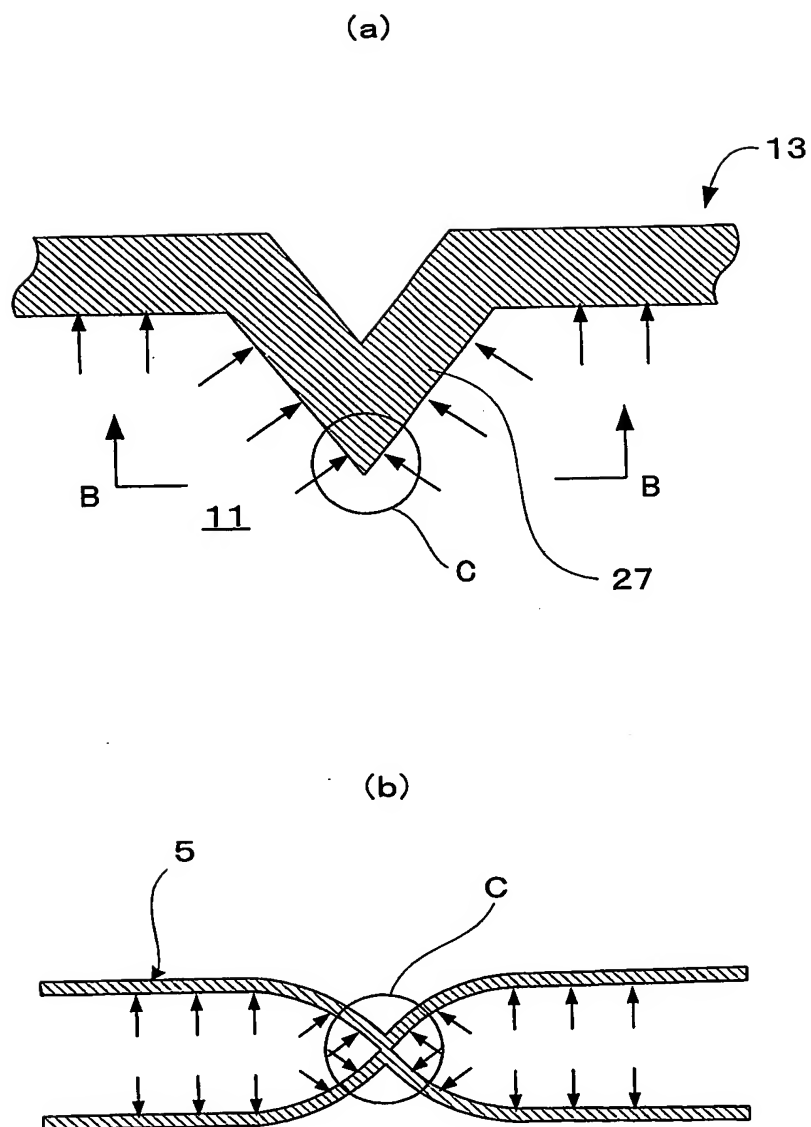
Fig. 9





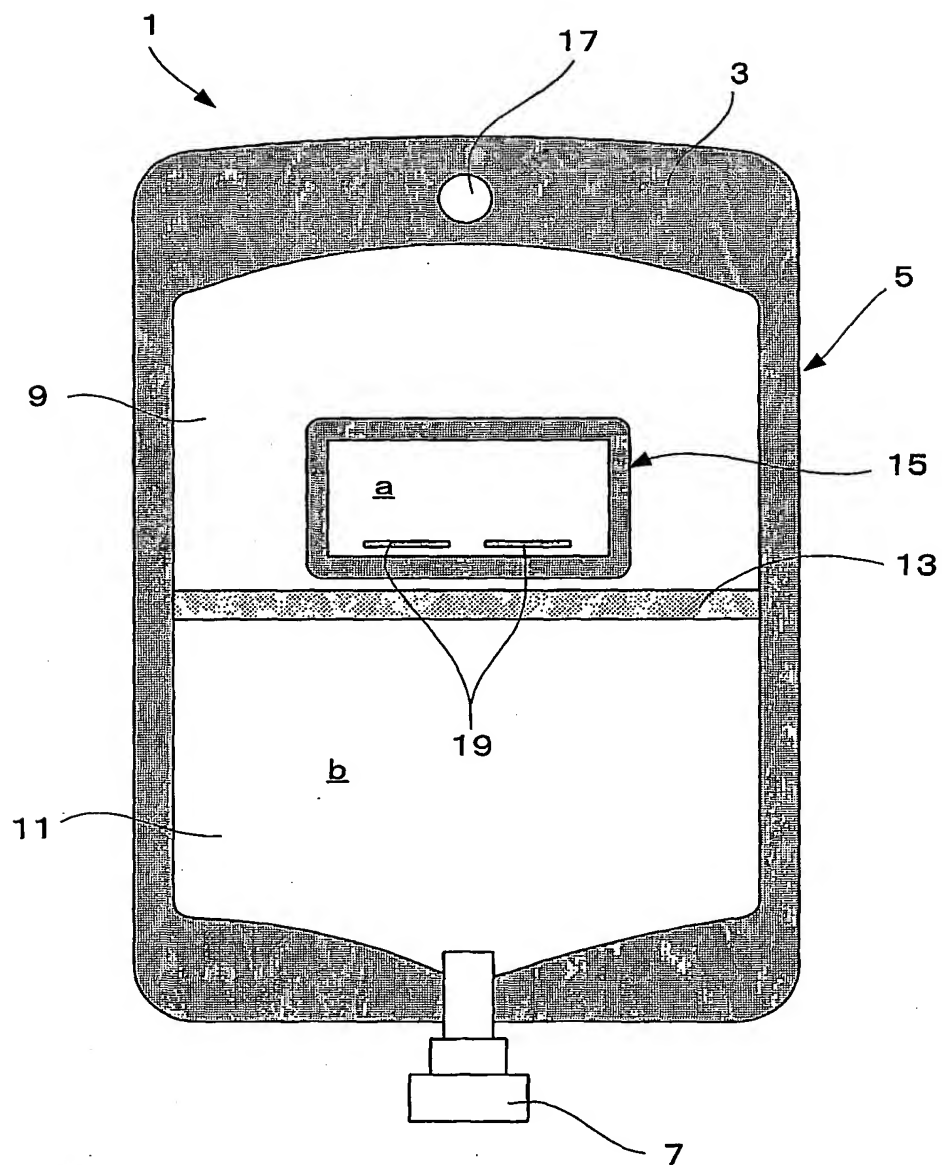
10/14

Fig. 10



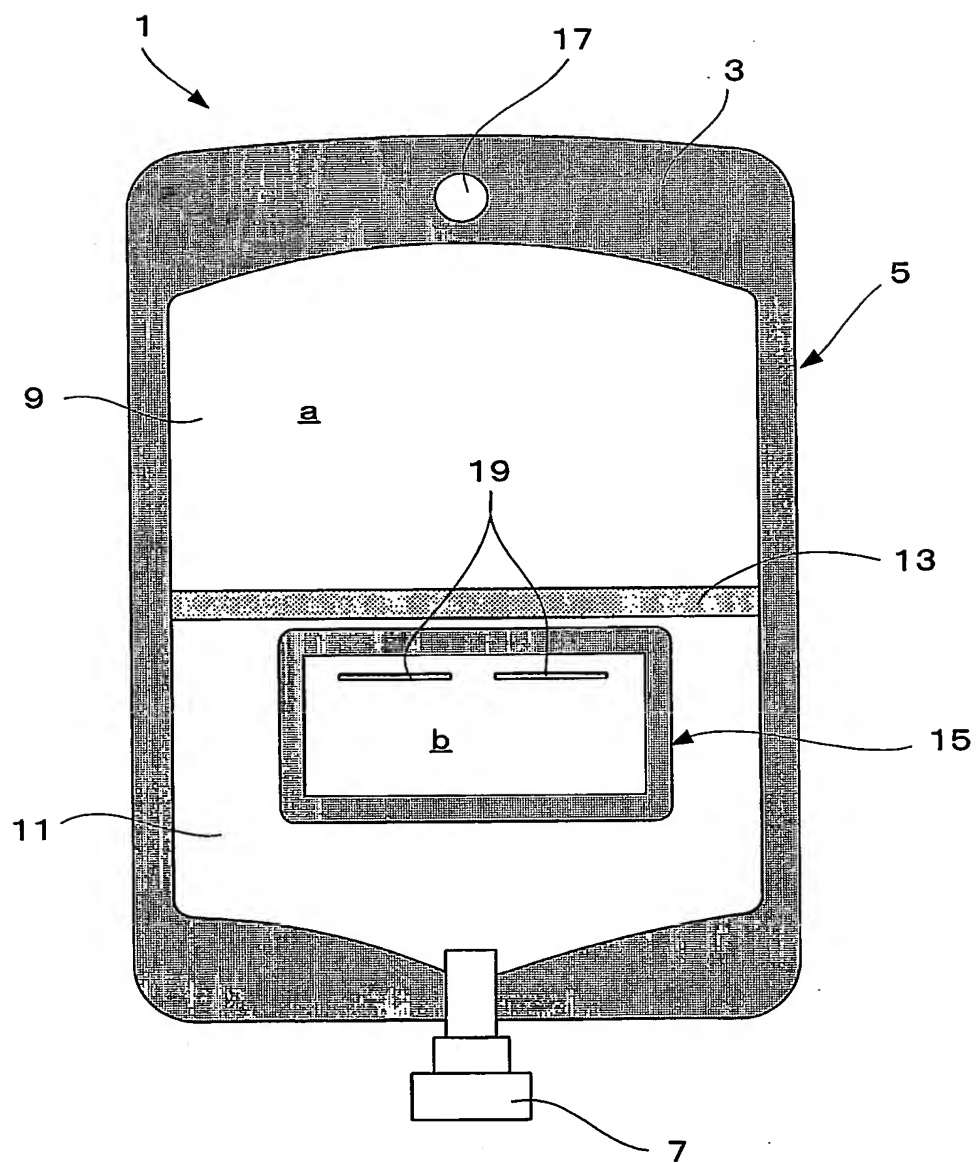
11/14

Fig. 11



12/14

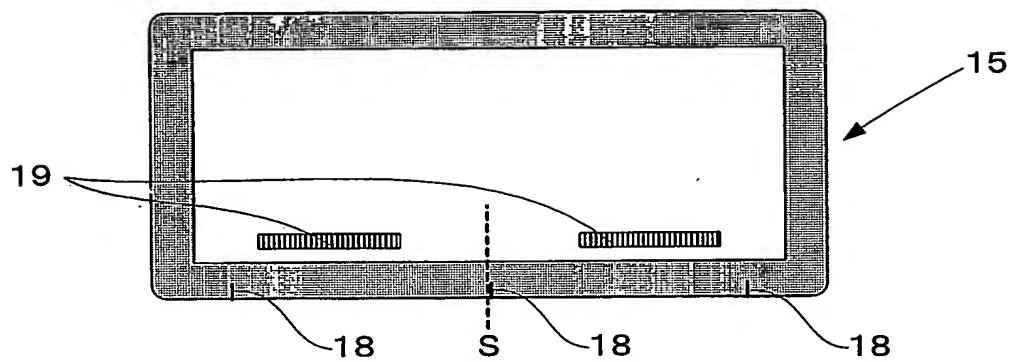
Fig. 12



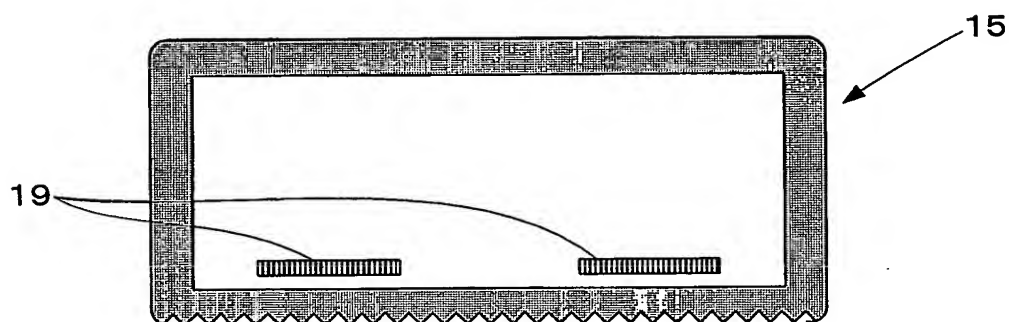
13/14

Fig. 13

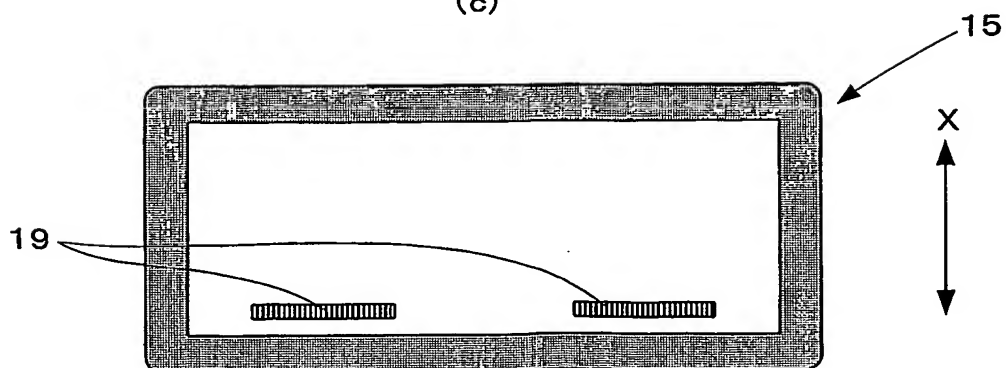
(a)



(b)

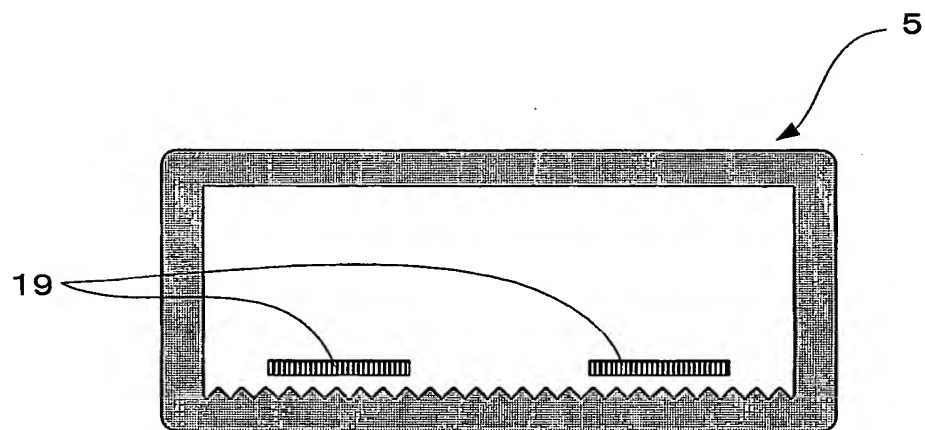


(c)



14/14

Fig. 14



## INTERNATIONAL SEARCH REPORT

International Application No

PCT/JP 03/05327

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61J1/10

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61J B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 602 910 A (LARKIN MARK E) 29 July 1986 (1986-07-29) column 3, line 39 -column 4, line 48; figures	1-13, 15, 16
X	US 5 462 526 A (BARNEY WARD W ET AL) 31 October 1995 (1995-10-31) column 4, line 12 - line 61 column 5, line 34 - line 44 figures 1,2	1, 12
X	US 6 036 004 A (BOWEN MICHAEL L) 14 March 2000 (2000-03-14) column 11, line 55 -column 12, line 3; figure 11	16
A	GB 951 300 A (ALBERT ALEXANDER ROBBINS) 4 March 1964 (1964-03-04) -/-	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*Z\* document member of the same patent family

Date of the actual completion of the international search

7 August 2003

Date of mailing of the international search report

14/08/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax (+31-70) 340-3016

Authorized officer

Godot, T

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/JP 03/05327

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>EP 0 639 364 A (OTSUKA PHARMA CO LTD)  22 February 1995 (1995-02-22)</p> <p>-----</p>	

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/JP 03/05327

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4602910	A	29-07-1986	NONE	
US 5462526	A	31-10-1995	AU 7729294 A WO 9507665 A1	03-04-1995 23-03-1995
US 6036004	A	14-03-2000	NONE	
GB 951300	A	04-03-1964	NONE	
EP 0639364	A	22-02-1995	JP 3079403 B2 JP 6014975 A AU 654442 B2 CA 2112661 A1 DE 69325801 D1 DE 69325801 T2 DK 639364 T3 EP 0639364 A1 FI 935972 A GR 3031088 T3 KR 209830 B1 NO 934910 A RU 2103987 C1 US 5423421 A AT 182464 T AU 4270993 A CN 1082881 A ,B EG 20103 A ES 2133399 T3 HU 68420 A2 WO 9321890 A1 PL 298768 A1 PT 101262 A ,B SG 44684 A1 ZA 9302950 A	21-08-2000 25-01-1994 03-11-1994 11-11-1993 02-09-1999 18-11-1999 29-11-1999 22-02-1995 24-02-1994 31-12-1999 15-07-1999 26-01-1994 10-02-1998 13-06-1995 15-08-1999 29-11-1993 02-03-1994 31-07-1997 16-09-1999 28-06-1995 11-11-1993 21-03-1994 30-06-1994 19-12-1997 30-12-1993